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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO.       |
|---|-------------|----------------------|-----------------------------------|------------------------|
| 10/682,372  | 10/10/2003  | Stig Olmar           | P08079US01/BAS                    | 6095                   |
| 881 7590 11/14/2007<br>STITES & HARBISON PLLC<br>1199 NORTH FAIRFAX STREET<br>SUITE 900<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>NATNITHITHADHA, NAVIN |                        |
|   |             |                      | ART UNIT<br>3735                  | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>11/14/2007           | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/682,372

**Applicant(s)**

OLLMAR ET AL.

**Examiner**

Navin Natnithadha

**Art Unit**

3735

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 19-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 19-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 14-15, 19, 20, and 25 have been amended. Claims 1-14 have been withdrawn. Claim 18 has been cancelled. Claims 30-43 have been added. Claims 1-17 and 19-43 are pending.
2. The objection to the Drawings is WITHDRAWN in view of the 13 Replacement Sheet (Figures 1-9), filed on 20 August 2007.

### ***Response to Arguments***

3. Applicant's arguments, see Remarks, p. 1, filed 20 August 2007, with respect to the prior Office Action stating that "a complete reply to [that] Office Action must include cancellation of non-elected claims or an appropriate action, citing 37 C.F.R. § 1.144 and M.P.E.P. § 821.01", have been fully considered and are persuasive. Therefore, the request that the non-elected claims be canceled or an appropriate action be taken is withdrawn.
4. Applicant's arguments, see Remarks, pp. 1-4, filed 20 August 2007, with respect to the rejection(s) of claim(s) 14-29 under 35 U.S.C. 102(e) as being anticipated by Kenan et al, US 6,788,966, have been fully considered and are persuasive. The 35 U.S.C. 102(e) rejection of claims 14-29 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below in regards to Davies, US 6,922,586 B2 ("Davies"), in view of Sieburg, US 7,103,398 B2 ("Sieburg").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14-17 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies in view of Sieburg.

Claims 14-17 and 19-29: As to claims 14-16, 19-21, and 27-29, Davies teaches a method for diagnosing a diseased condition of the skin (see Abstract and figs. 1-4), the method comprising the steps of:

(i) placing an electrical conducting probe ("probe device") 105/400 against a skin surface of the subject (see fig. 4A), wherein the probe 105/400 comprises a plurality of electrodes (see fig. 3), wherein a first electrode ("current passing electrodes") 5 and a

second electrode (first ring of "voltage sensing electrodes") 8 of the plurality of electrodes are spaced a first distance from each other and wherein the first electrode 5 and a third electrode (second, inner ring of "voltage sensing electrodes") 8 of said plurality of electrodes are spaced a second distance from each other;

(ii) passing an electrical current through the electrodes to obtain a value of skin impedance, wherein said electrical current is separately passed between the first electrode 5 and the second electrode (first ring of "voltage sensing electrodes") 8 and between the first electrode 5 and the third electrode (second, inner ring of "voltage sensing electrodes") 88 to obtain at least a first value of impedance and at least a second value of impedance (see fig. 3 and col. 11, ll. 36-44, and col. 11, l. 64, to col. 12, l. 12); and

(iii) using reference data to determine whether the impedance value indicates the diseased condition, such as skin cancer (see col. 8, ll. 60-65, col. 9, ll. 48-65, col. 9, l. 66, to col. 10, l. 19, and col. 11, ll. 1-4).

Davies does not teach "each electrode furnished with a number of spikes, the spikes being laterally spaced apart from each other and being of sufficient length to penetrate the stratum corneum" in claim 1, along with the subject matter of claims claims 17 and 22-26, which directed to the amount and dimensions of the spikes. However, Sieburg teaches a method for "electrical signal sensor and/or signal application" (see Abstract and figs. 1-8), comprising: electrodes 16 furnished with a number of spikes 34 having a variety of dimensions (see para. [0059], [0061], and [0063]). Therefore, it would have been obvious for one of ordinary skill in the art at the

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time the invention was made to modify Davies's electrode structure with Sieburg because Sieburg discloses the following passage directed to the advantage of including need-like electrode configurations to the type of electrical sensing/application to human or animal tissue (see para. [0026]):

Arrays of needles or needle-like configurations are of primary interest for the medical diagnosis and therapy of the skin or other organs and tissues of humans and animals. Such an array of electrodes, however, might also be useful for other configurations whenever it is possible to establish electrical contact with the component to be investigated and when the determination of an impedance or electrical image provides meaningful information. This typically applies to components which do not have a hard outer surface because in this case only individual electrodes would establish an electrical contact. Therefore, components of interest are typically softer on their surface like elastomeric and similar components.

In fact, a particular area of interest in medical diagnosis disclosed by Seiburg is the diagnosis of cancer (see Seiburg, para. [0005]). Furthermore, Davies discloses that "[t]he system 100 interfaces with a probe device 105 including multiple electrodes, wherein the actual implementation of the probe device 105 depends on the organ and condition under test" (see Davies, col. 10, ll. 60-66), and thus, suggests that other multiple electrode configurations can be used depending on the tissue under testing, such as the invention disclosed by Sieburg.

Claims 30-43: Because Applicant stated that the added new apparatus claims 30-43 correspond to method claims 14-17, 19-27, and 29, respectively, and are not independent and distinct inventions, the claims 30-43 are rejected for the same reasons as stated above for claims 14-17, 19-27, and 29.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Primary Examiner, Art Unit 3735  
11/13/2007